

Whey Peptides, WPC 80, ION EXCHANGE whey protein, lactoferrin, whey protein, milk protein, casein, ~~chicken egg albumin~~ and soy.

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### **REMARKS**

Reconsideration and allowance of the subject application in light of the foregoing amendments and Remarks below is hereby requested. The claims now pending in this application are: 1, 3-5, 7, 8, 10-16, 18-25, 27-29, 31-34, 36-38, 40-43, 45-47, 49-59 and 62-67.

### **Claim Objection**

The misspelled term "arginnie" in claim 43 has now been corrected to "arginine," applicants respectfully request this claim objection be withdrawn.

### **Claim Rejections - 35 U.S.C. § 112**

Claims 1, 13, 20-24, 28, 37, 46, 53-57 and 64 have been amended and claim 63 cancelled to correct informalities and incorporate the Examiner's suggestions in the subject Office Action. Applicants respectfully submit that WPI 97, Whey Peptides, WPC 80, ION EXCHANGE whey protein are well-established terms for specific ingredients that are well-known in the art of food industry. (*See*, for example, enclosed product manufacturer's information).

Accordingly, the rejections of these claims under 35 U.S.C. § 112 should be withdrawn.

### **Claim Rejections - 35 U.S.C. § 102/103**

i) Claims 1, 8, 13-17, 58, 59 and 64 stand rejected as anticipated under 35 U.S.C. § 102 by, or in the alternative, under 35 U.S.C. § 103 (a) as obvious in view of Schneider et al. (U.S. Pat. No., 5,902,829)

To anticipate a claim, a prior art reference must disclose each and every limitation of the claimed invention. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Schneider et al. fail to disclose "a substance that increases nitric oxide production selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, folic acid and glucomannan (*See*, newly amended claims.) Hence, Schneider cannot be an anticipatory reference under 35 U.S.C. § 102(e).

Schneider et al. merely speculate on the use of folic acid as one of many vitamins that may be incorporated (col. 4, lines 9-26) into the claimed formulation of L-arginine, a precursor of L-arginine and/or physiologically acceptable salts thereof, and a nutritionally acceptable carrier but for a different purpose (amelioration of micro-circulatory hypo-perfusion). Schneider et al. fail to teach any specific formulation that is in fact comprised L-arginine, a source of amino acids, and at least one substance which increases nitric oxide production selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, folic acid and glucomannan. Accordingly, Schneider fails to meet each and every limitation and as such, cannot be an anticipatory reference under 35 U.S.C. § 102(e).

Schneider is directed to a method for modulating microcirculation in a patient in need of such modulation. The point here is that there is no basis for choosing any from the numerous compounds disclosed by Schneider.

Schneider et al. fail to provide any motivation or suggestion for a substance that increases nitric oxide production selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, folic acid and glucomannan. Similarly, Schneider et al. lacks the sufficient motivation for a formulation as claimed and for the purpose as claimed in the present invention. Hence, Schneider reference cannot support the rejection under 35 U.S.C. § 103(a).

In sum, Schneider et al. fail to teach or suggest the nutritional composition of the present invention comprising a substance for increasing nitric oxide production consisting of glycosidal saponins, ginseng, N-acetyl cysteine, folic acid and glucomannan for increasing lean mass and strength.

ii) Claims 1,3,8,13-18, 25, 27, 34, 36, 37, 43, 45, and 58 stand rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious in views of Portman.

Portman et al., like Schneider et al., fail to disclose any substance known to increase nitric oxide production, let alone a group consisting glycosidal saponins, ginseng, N-acetyl cysteine, folic acid and glucomannan for increasing lean muscle mass and strength. Hence, Portman reference fails to meet each and every limitation of the claims of the present invention and therefore cannot be an anticipatory reference under 35 U.S.C. § 102(e).

Because Portman et al. fails to provide any teaching or suggestion for nitric oxide

component, it cannot support for rejections under §§102(e) and 103.

iii) Claims 1,3-5,7,8,10-16,18-25,27-29,31-34,36-38,40-43,45-47,49-59,62-67 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Portman in view of Doi et al., Kim et al., Droge, Larner et al., Jableck et al., Maxwell et al., Food Chem. News and Kolla et al.

Portman, Doi et al., Droge, Larner et al., Food chem. News and Jablecki et al., all fail to disclose an ingredient which increases nitric oxide production or for that matter any of glycosidal saponins, ginseng, N-acetyl cysteine, folic acid and glucomannan. Nor do these references disclose an ingredient which increases nitrogen retention in the body. While Kim discloses “ginseng promotes nitric oxide” and Maxwell discloses “amino acids including arginine that increase endogenous nitric oxide”, both Kim and Maxwell et al. fail to disclose or suggest the claimed combination of ingredients or a method for increasing lean mass and strength.

Applicants submit that the Examiner fails to establish a *prima facie* case of obviousness.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination.

*ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed.Cir. 1984).

Portman, Doi et al., Kim et al., Droge, Larner et al., Jableck et al., Maxwell et al., and Food Chem. News, all fail to a method for supplementing the diet of an athlete an effective amount of ingredients in order to increasing muscle mass and/or strength (e.g., claim 28).

While these references disclose some of the ingredients recited in the instant claims for use in the food products they clearly do not teach or suggest the claimed combination ingredients. Moreover, nothing in these references even remotely suggests to those skilled in the art that whatever the ingredients are disclosed could be successfully combined in the instantly claimed combination(s) to provide a useful food supplement for enhancing lean muscle mass and strength. For the reasons stated above, it is submitted that the cited references cannot be 103(a) prior art.

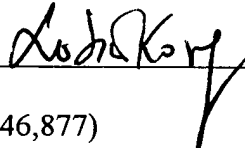
Accordingly, the rejection of claims 1, 3-5, 7, 8, 10-16, 18-25, 27-29, 31-34, 36-38, 40-43, 45-47, 49-59, 62-67 under 35 U.S.C. 103(a), over Portman (arginine, whey protein, and ginseng), Doi (glucomannan), Kim (saponins derived from ginseng), Droge (N-acetyl cysteine), Larner (d-chiro-inositol), Jableck (inositol into phosphatidylinositol), Maxwell (arginine, folic

acid, taurine), Food Chem. News (pinitol), Kolla (lipoic acid) are improper and should be withdrawn.

Applicants respectfully submit that the application is now in condition for allowance, and solicit such action at an early date. The Examiner is invited to telephone the undersigned attorney at (212) 908-6018 if there are any questions concerning this amendment.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (2x Amended) A food supplement comprising L-arginine, a source of amino acids and at least one substance which increases nitric oxide production selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, [and] folic acid and glucomannan.
4. (2x Amended) A food supplement comprising L-arginine, a source of amino acids and at least one substance which can enhance and/or mimic insulin activity selected from the group consisting of N-acetyl cystein, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, glucomannan and d-pinitol.
13. (2x Amended) The food supplement according to any one of claims 1 [to 12] 3-5, 7,8 and 10-12, wherein the source of amino acids is selected from the group consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, and whey protein.
20. (2x Amended) The food supplement according to claim 19 [comprising 150 mg to 1500 mg glycosidal saponins; about 100 mg to 2000 mg myo-inositol; and 25 mg to 2000 mg glucomannan], wherein the amount of glycosidal saponins is 150 mg to 1500 mg; the amount of myo-inositol is about 100 mg to 2000 mg; and the amount of glucomannan is 25 mg to 2000 mg.
21. (2x Amended) The food supplement according to claim 19 [comprising 50 mg to 500 mg glycosidal saponins; about 200 mg to 1000 mg myo-inositol; and 50 mg to 1000 mg glucomannan], wherein the amount of glycosidal saponins is 50 mg to 500 mg; the amount of myo-inositol is about 200 mg to 1000 mg; and the amount of glucomannan is 50 mg to 1000 mg.
22. (2x Amended) The food supplement according to claim 19 [comprising 100 mg to 500 mg glucomannan], wherein the amount of glucomannan is 100 mg to 500 mg.

23. (2x Amended) The food supplement according to claim 19 [comprising about 50 mg glycosidal saponins] , wherein the amount of glycosidal saponins is about 50 mg.
24. (2x Amended) The food supplement according to any of claims 19-23, wherein the source of amino acids is whey protein.
25. (2x Amended) A method for supplementing the diet of an athlete, comprising administering as part of the diet [of the athlete] an effective amount of a supplement comprising L-arginine, a source of amino acids and at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, glucomannan and folic acid.
28. (2x Amended) A method for supplementing the diet of an athlete, comprising administering as part of [to] the diet [of the athlete] an effective amount of a supplement comprising L-arginine, a source of amino acids and at least one substance which can enhance and/or mimic insulin activity selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyll-inositol, d-chiro-inositol, l-chiro-inositol, glucomannan and d-pinitol.
34. (2x Amended) A method for increasing muscle mass and/or strength of an individual, comprising administering as part of [to] the diet of an [the] athlete of an effective amount of L-arginine, a source of amino acids, and at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, and folic acid.
37. (2x Amended) A method for increasing muscle mass and/or strength of an individual comprising administering as part of [to] the diet of an [the] athlete an effective amount of L-arginine, a source of amino acids and at least one substance which can enhance and /or mimic insulin activity selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, glucomannan and d-pinitol.

43. (2x Amended) A method for supplementing the diet of an athlete, comprising administering as part of [to] the diet of an [the] athlete an effective amount of supplement comprising [L-arginine] L-arginine, whey protein and at least one substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, glucomannan and folic acid.
46. (2x Amended) A method for supplementing the diet of an athlete, comprising administering as part of [to] the diet of an [the] athlete an effective amount of L-arginine, whey protein, and at least one substance which can enhance and/or mimic insulin activity selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-inositol, d-chiro-inositol, l-chiro-inositol, glucomannan, and d-p-pinitol.
53. (2x Amended) The method according to claim 52, wherein the [supplement comprises 150 mg to 1500 mg glycosidal saponins; about 100 mg to 2000 mg myo-inositol; and 25 mg to 2000 mg glucomannan] amount of glycosidal saponins is 150 mg to 1500 mg; the amount of myo-inositol is about 100 mg to 2000 mg; and the amount of glucomannan is 25 mg to 2000 mg.
54. (2x Amended) The method according to claim 52, wherein the [supplement comprises 50 mg to 500 mg glycosidal saponins; about 200 mg to 1000 mg myo-inositol; and 50 mg to 1000 mg glucomannan] amount of glycosidal saponins is 50 mg to 500 mg; the amount of myo-inositol is about 200 mg to 1000 mg; and the amount of glucomannan is 50 mg to 1000 mg.
55. (2x Amended) The method according to claim 52, wherein the [supplement comprises 100 mg to 500 mg glucomannan] amount of glucommnan is 100 mg to 500 mg.
56. (2x Amended) The method according to claim 52, wherein the [supplement comprises 50 mg glucosidal saponins] amount of glucosidal saponins is 50 mg.

57. (2x Amended) The method according to any one of claims 52-56, wherein the [amino acid comprises whey protein] source of amino acid is whey protein.
64. (2x Amended) The food supplement according to any one of claims 1[-12] 3-5, 7,8 and 10-12, wherein the source of amino acids is selected from the group consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, whey protein, milk protein, casein, chicken egg albumin and soy.